K09 4020

510(k) SUMMARY

Ranir, LLC's
Grind No More Generation II

JAN 25 2010

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

Jonathan S. Kahan
Regulatory Counsel to Ranir, LLC
Hogan & Hartson LLP
555 Thirteenth Street, N.W.
Washington, DC 20004

Phone: (202) 637-5794
Facsimile: (202) 637-5910

Date Prepared: December 10, 2009

Name of Device and Name/Address of Sponsor

Grind No More Generation II

Ranir, LLC
4701 East Paris Avenue SE
Grand Rapids, MI 49512

Phone: (616) 698-8880
Facsimile: (616) 656-7650

Common or Usual Name

Mouthguard

Classification Name

Mouthguard, Over-the-Counter

Classification Product Code

OBR

Predicate Devices

Ranir, LLC's Grind No More 2 (K091175)
Ranir, LLC's Rest Assured Nite Protector (K063229)

Purpose of the Special 510(k) notice.

The Grind No More Generation II is a modification to Ranir's Grind No More 2 (K091175).

Intended Use

Grind No More Generation II is indicated for use for protection against bruxism or nighttime teeth grinding. The device is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Technological Characteristics

Grind No More Generation II is an anterior and posterior occlusive mouthguard, consisting of two molar bite plates and an anterior bite plate connected by a buccal retention band. As with the predicate Grind No More 2, the molar bite plates are grooved with vertical positioners to engage the natural anatomy of the teeth for enhanced retention. The Grind No More Generation II has a similar design to the Grind No More 2, with the addition of the anterior bite plate. However, there are multiple FDA cleared mouthguards that incorporate both anterior and posterior occlusion, such as the predicate Rest Assured. Therefore, the Grind No More Generation II is technologically similar to the predicate devices.

Substantial Equivalence

Grind No More Generation II is as safe and effective as the predicate devices. Grind No More Generation II has the same intended uses and similar indications, technological characteristics, and principles of operation as the predicate devices. The minor technological differences between Grind No More Generation II and the predicate devices raise no new questions of safety or effectiveness. Thus, the Grind No More Generation II is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 25 2010

Ranir LLC
C/O Mr. Jonathan S. Kahan
Regulatory Counsel
Hogan and Hartson LLP
555 Thirteenth Street, N.W.
Washington, District of Columbia 20004

Re: K094020
Trade/Device Name: Grind No More Generation II
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: OBR
Dated: December 29, 2009
Received: December 29, 2009

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K094020

Device Name: Grind No More Generation II

Indications for Use:

The Grind No More Generation II is indicated for use for protection against bruxism or nighttime teeth grinding. The device is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Prescription Use _____ AND/OR Over-The-Counter Use X
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

B Sbetz DDS for Dr. K. P. Mulay
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K094020